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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,523

03/24/2006

Thomas W Hodge

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EXAMINER

BOESEN, AGNIESZKA

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/535,523	<b>Applicant(s)</b> HODGE ET AL.	
	<b>Examiner</b> AGNIESZKA BOESEN	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 46, 72 and 73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46, 72 and 73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

The Amendment filed 5/29/2009 in response to the Office Action of 3/30/2009 is acknowledged and has been entered. Claims 43-45, 49, 50, 69-71 and 74-76 have been canceled. Claim 45 has been amended. Claims 46, 72 and 73 are under examination.

Upon further consideration the Finality of the Office action of 3/30/2009 is withdrawn to make the rejections present in this Office action.

#### *New Rejection*

#### ***Claim Rejections - 35 USC § 112***

Claims 46, 72 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 recites the limitation "binding of the HIV protein to the target protein" in the last line of the claim. There is insufficient antecedent basis for this limitation in the claim. It is understood that the host protein encoded by the Rab9 target sequence is binding to the HIV protein. Correction and/or clarification is required.

The limitation "wherein the host protein is a protein encoded by a Rab9 target sequence that comprises SEQ ID NO: 118" in claim 46 encompasses a protein that comprises the full-length sequence of encoded by SEQ ID NO: 118 or any portion of that protein. The claim is anticipated by a dipeptide or any short peptide encoded by a portion of SEQ ID NO: 118. Correction and/or clarification is required.

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***Claim Rejections - 35 USC § 103***

Rejection of claims 43-45, 49, 50 and 69 under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (US Patent Application Publication 2003/0166870 A1) in view of Hanna et al. (PNAS, May 2002, Vol. 99, p. 7450-7454) as evidenced by Blot et al. (Journal of Virology, June 2003, Vol. 77, p. 6931-6945) **is moot** because Applicant canceled the claims.

***New Rejection***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 46, 72 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (US Patent Application Publication 2003/0166870 A1) in view of Hanna et al. (PNAS, May 2002, Vol. 99, p. 7450-7454) and Muzny et al. (Accession number AC 079383, 2000, p. 1-64) as evidenced by Blot et al. (Journal of Virology, June 2003, Vol. 77, p. 6931-6945).**

The present claims recite “wherein the host protein is a protein encoded by a Rab9 target sequence that comprises SEQ ID NO: 118” in claim 46 encompasses a protein that comprises the full-length sequence of encoded by SEQ ID NO: 118 or any portion of that protein. The claim is anticipated by a dipeptide or any short peptide encoded by a portion of SEQ ID NO: 118.

Additionally the claims recite: “contacting the host protein with the HIV protein and a test compound, wherein the host protein is a protein encoded by a Rab9 target sequence that comprises SEQ ID NO: 118 or SEQ ID NO: 119 or hybridizes under high stringency conditions

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to a Rab9 target sequence comprising SEQ ID NO: 118 or SEQ ID NO: 119, wherein the high stringency conditions comprise hybridization at 42 °C with a hybridization solution comprising 5X SSC and a wash with a wash solution comprising 2X SSC at 65 °C".

It is herein interpreted that the host protein of the present invention is any protein encoded by a nucleic acid sequence that hybridizes to the SEQ ID NO: 118 or SEQ ID NO: 119. Additionally, the claims only require a portion of the host protein.

Wu et al. teach methods of identifying an agent that decreases binding of HIV envelope protein to CCR5 chemokine receptor thereby decreasing the HIV virus infecting the cell through the CD4 T cell receptor, the methods comprise contacting the T cell receptor host cell protein with the envelope protein of an HIV virus, the test compound and an antibody binding CCR5, and determining whether binding of the viral protein to the host protein is decreased in the presence of the test compound/agent (see claims 57-68 and [0083], [0084], [0110], [0112], [0196], [0198]). The methods taught by Wu et al. comprise expressing the host protein in a cell and contacting the host protein with the HIV envelope protein and a test compound (see [0012], [0013], [0021], [0061], [0078], [0086], [0155] and [0156]. The viral protein comprises a label and the method comprises detecting the amount of the label in order to determine whether the binding of the HCV envelope protein to T cell receptor has decreased (see [0084]).

Wu et al. does not teach host protein Rab9.

Hanna et al. teach that Rab9 protein binds the vesicle cargo selection protein TIP47 and facilitates the transport of proteins from endosomes to trans Golgi network (see Abstract and Discussion). Blot provides evidence that HIV envelope glycoprotein is located in the trans-Golgi network and teaches that Rab9 bound to TIP47 interacts with the cytoplasmic tail of the HIV

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envelope glycoprotein subunit p41 and is critical for the incorporation of HIV envelope glycoprotein into mature virions (see the entire document).

Muzny teaches Rab9 wild-type nucleic acid sequence that hybridizes to present SEQ ID NO: 118. Any protein that is encoded by Muzny's nucleic acid, including a wild-type Rab9 protein reads on the host protein of the present invention.

It would have been *prima facie* obvious to provide Wu's method of identifying an agent that decreases binding of HIV envelope protein to Hanna's Rab9 protein encoded by Muzny's nucleic acid sequence that hybridizes to present SEQ ID NO: 118, the method comprising contacting Rab9 protein with the test compound and the HIV protein and determining whether binding of the HIV protein to the Rab9 protein is decreased in the presence of the test compound because Rab9 protein has been known to facilitate the transport of proteins (including viral proteins) from the endosomes to trans Golgi as taught by Hanna. It would have been obvious to substitute Hanna's Rab9 protein for Wu's T cell receptor host protein.

One would have been motivated to use Rab9 protein as a host protein in Wu's assay for identifying compounds that decrease binding of HIV protein to Rab9 host cell protein because Hanna teaches that Rab9 protein facilitates the transport of proteins from endosomes to trans Golgi network and because Blot provides the evidence that HIV envelope protein is transported from the endosomes to trans Golgi where it resides.

One would have had a reasonable expectation of success to practice the claimed methods because Wu provides evidence that laboratory methods involving cell signaling have been known in the art at the time of the present invention.

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Thus the invention as whole would have been *prima facie* obvious to the skilled artisan at the time when the invention was made.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AGNIESZKA BOESEN whose telephone number is (571)272-8035. The examiner can normally be reached on Monday through Friday from 9:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached at 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen/  
Examiner, Art Unit 1648